PMA Monthly approvals from 9/1/2016 to 9/30/2016

Original

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150021	09/23/2016	PMAO - PMA Origi	FREESTYLE LIBRE PRO FLASH GLUCOSE MONITORING SYSTEM	ABBOTT DIABETES CARE INC.	The FreeStyle Libre Pro Flash Glucose Monitoring System is a professional continuous glucose monitoring (CGM) device indicated for detecting trends and tracking patterns in persons (age 18 and older) with diabetes. The System is intended for use by health care professionals and requires a prescription. Readings from the FreeStyle Libre Pro Sensor are only made available to patients through consultation with a health care professional. The System does not require user calibration with blood glucose values. The FreeStyle Libre Pro System aids in the detection of glucose level excursions above or below the desired range, facilitating therapy adjustments. Interpretation of the FreeStyle Libre Pro Flash Glucose Monitoring System readings should be based on the trends and patterns analyzed through time using the reports available.
P150040	09/13/2016	PMAO - PMA Origi	VISUMAX FEMTOSECOND LASER	CARL ZEISS MEDITEC, INC.	Approval for the VisuMax Femtosecond Laser. This device is indicated for use in small incision lenticule extraction (SMILE) for the reduction or elimination of myopia >= -1.00 D to <= -8.00 D, with <= -0.50 D cylinder and MRSE <= -8.25 D in the eye to be treated in patients who are 22 years of age or older with documentation of stable manifest refraction over the past year as demonstrated by a change of <= 0.50 D MRSE.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P150044	09/28/2016	PMAO - PMA Origi	COBAS EGFR MUTATION TEST V2	ROCHE MOLECULAR SYSTEMS, INC.	The cobas® EGFR Mutation Test v2 is a real-time PCR test for the qualitative detection of defined mutations of the epidermal growth factor receptor (EGFR) gene in non-small cell lung cancer (NSCLC) patients. Defined EGFR mutations are detected using DNA isolated from formalin-fixed paraffin-embedded tumor tissue (FFPET) or circulating-free tumor DNA (cfDNA) from plasma derived from EDTA anti-coagulated peripheral whole blood. The test is indicated as a companion diagnostic to aid in selecting NSCLC patients for treatment with the targeted therapies listed in Table 1 below in accordance with the approved therapeutic product labeling: Table 1 Drug FFPET Plasma TARCEVA® (erlotinib) Exon 19 deletions and L858R Exon 19 deletions and L858R TAGRISSO (osimertinib) 790M T790M* Patients with positive cobas® EGFR Mutation Test v2 test results using plasma specimens for the presence of the EGFR mutations listed above are eligible for treatment with the corresponding drug as indicated in Table 1 (see Note* for T790M). Patients who are negative for these mutations by this test should be reflexed to routine biopsy and testing for EGFR mutations with the FFPET sample type. *The efficacy of TAGRISSO (osimertinib) has not been established in the EGFR T790M plasma-positive, tissue-negative or unknown population and clinical data for T790M plasma-positive patients are limited; therefore, testing using plasma specimens is most appropriate for consideration in patients from whom a tumor biopsy cannot be obtained. Drug safety and efficacy have not been established for the EGFR mutations listed in Table 2 below that are also detected by the cobas® EGFR Mutation Test v2: Table 2 Drug FFPET Plasma TARCEVA® (erlotinib) G719X, exon 20 insertions, T790M, S768I and L861Q G719X, exon 20 insertions, T790M, S768I and L861Q TAGRISSO (osimertinib) G719X, exon 19 deletions, L858R, exon 20 insertions, S768I, and L861Q G719X, exon 19 deletions, L858R, exon 20 insertions, S768I, and L861Q For manual sample preparation, FFPET specimens are processed using the cobas® DNA Sample Preparation Kit and plasma specimens are processed using the cobas® cfDNA Sample Preparation Kit. The cobas z 480 analyzer is used for automated amplification and detection.
P160001	09/08/2016	PMAO - PMA Origi	OBALON BALLOON SYSTEM	OBALON THERAPEUTICS, INC.	Approval for the Obalon Balloon System. The device is a swallowable intragastric balloon system indicated for temporary use to facilitate weight loss in adults with obesity (BMI of 30 to 40 kg/m2) who have failed to lose weight through diet and exercise. The System is intended to be used as an adjunct to a moderate intensity diet and behavior modification program. All balloons must be removed 6 months after the first balloon is placed.

P160017	09/28/2016	PMAO - PMA Origi	MINIMED 670G SYSTEM	MEDTRONIC MINIMED	MiniMed 670G System The Medtronic MiniMed 670G system is intended for continuous delivery of basal insulin (at user selectable rates) and administration of insulin boluses (in user selectable amounts) for the management of Type 1 diabetes mellitus in persons, fourteen years of age and older, requiring insulin as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin. The MiniMed 670G System includes SmartGuard technology, which can be programmed to automatically adjust delivery of basal insulin based on Continuous Glucose Monitor sensor glucose values, and can suspend delivery of insulin when the sensor glucose value falls below or is predicted to fall below predefined threshold values. The Medtronic MiniMed 670G System consists of the following devices: MiniMed 670G insulin pump, the Guardian Link (3) Transmitter, the Guardian Sensor (3), One-Press Serter, and the Contour NEXT Link 2.4 Glucose Meter. The system requires a prescription. The Guardian Sensor (3) glucose values are not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a finger stick may be required. All therapy adjustments should be based on measurements obtained using a home glucose monitor and not on values provided by the Guardian Sensor (3). Guardian Sensor (3) The Guardian Sensor (3) is intended for use with the MiniMed 670G system to continuously monitor glucose levels in persons with diabetes. It is intended to be used for detecting trends and tracking patterns in persons aged fourteen years and older, and to be used by the MiniMed 670G system to automatically adjust basal insulin levels. It is indicated for use as an adjunctive device to complement, not replace, information obtained from standard blood glucose monitoring devices. The sensor is intended for single use and requires a prescription. The Guardian Sensor (3) is indicated for 7 days of continuous use. One-press Serter The One-press Serter is used as an aid for inserting the sensor. It is indicated for single-patient use and it is not intended for multiple-patient use. Guardian Link (3) Transmitter The Guardian Link (3) Transmitter is intended for use with the MiniMed 670G System. The Guardian Link (3) Transmitter powers the glucose sensor, collects and calculates sensor data, and wirelessly sends the data to the MiniMed 670G insulin pump. The Transmitter is intended for single-patient multi-use. Contour NEXT Link 2.4 Glucose Meter The Contour Next Link 2.4 Wireless Blood Glucose Monitoring System is an over the counter (OTC) device utilized by persons with diabetes in home settings for the measurement of glucose in whole blood, and is for single patient use only and should not be shared. The Contour Next Link 2.4 wireless blood glucose monitoring system is indicated for use with fresh capillary whole blood samples drawn from the fingertip and palm only. The Contour NEXT Test Strips are intended for self-testing by persons with diabetes for the quantitative measurement of glucose in whole blood samples from 20 to 600 mg/dL. The Contour Next Link 2.4 wireless blood glucose monitoring system is intended to be used to transmit glucose values to the MiniMed 670G pump and facilitate transfer of information to Medtronic CareLink Software through the use of radio frequency communication. The Contour Next Link 2.4 Wireless Blood Glucose Monitoring System is not intended for the diagnosis of, or screening for, diabetes mellitus. It is not intended for use on neonates.

Total: 5

Supplements

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S039	09/20/2016	S - Special CBE	SURGICEL ABSORBABLE HEMOSTAT	ETHICON, INC.	Approval for the addition of second sensor on the band sealing equipment that seals the open side of the foil pouch of the SURGICEL Family of Absorbable Hemostats and GYNECARE INTERCEED Absorbable Adhesion Barrier products manufactured at Ethicon, Sarl.
P830055/S172	09/22/2016	R - Real-Time Proc	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Approval to add the ATTUNE Cementless Rotating Platform (RP) Tibial Bases to LCS Total Knee System. The subject device adds POROCOAT porous coating to fixation surfaces of the previously approved ATTUNE Cemented RP Tibial Bases.
P830061/S127	09/07/2016	N - Normal 180 Day	CAPSURE SENSE MRI SURESCAN LEAD MODEL 4074, CAPSURE SENSE MRI SURESCAN LEAD MODEL 4574	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for 1.5 and 3T MR-conditional labeling for MRI SureScan lead Models 4074, 4574, and 4076 when used with currently approved SureScan MR-conditional devices.
P840001/S343	09/28/2016	S - Special CBE	RESTORE, ITREL, AND SYNERGY SPINAL CORD STIMULATION SYSTEMS AND PISCES SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Approval for updates to the labeling for the Medtronic Specify 5-6-5 and 2x8 surgical leads to clarify that these are not intended for test stimulation outside of the operating room.
P860004/S250	09/09/2016	R - Real-Time Proc	ASCENDA INTRATHECAL CATHETER WITH 86 CM SPINAL SEGMENT, 66CM SPINAL SEGMENT, 86 CM SPINAL SEGMENT REVISION KIT, ACCESSORY KIT.	MEDTRONIC INC.	Approval for the addition of a low-PFOA (perfluorooctanoic acid) polytetrafluoroethylene (PTFE) coating to the Anchor Dispenser Tool (ADT) to address customer complaints of difficulty deploying the Ascenda anchor from the Anchor Dispenser Tool; the addition of the flare to the hypotube; the updated materials list in the Ascenda Implant Manual and minor changes to dimension tolerances on the Anchor Dispenser Tool.
P860004/S257	09/27/2016	R - Real-Time Proc	ASCENDA INTRATHECAL CATHETERS AND KITS	MEDTRONIC INC.	Approval for labeling changes for Medtronics Ascenda Intrathecal Catheter and Revision Kit including: Implant Manuals Catheter Length Measurement; Implant Manuals Materials Table; Implant Manuals Verb change; Implant Manuals Reference to Model 8784 Kit added; Implant Manuals Other clarification, administrative and style changes; Package Labels Catheter Length Measurements; Package Labels Addition of symbols; Package Labels Other minor changes. These changes impact the manuals associated with the following models: Full Catheter Kit 8780 Ascenda Intrathecal Catheter (86cm spinal segment); Full Catheter Kit 8781 Ascenda Intrathecal Catheter (66cm spinal segment); Revision Catheter Kit 8782 Ascenda Intrathecal Catheter (86cm spinal segment revision kit); Revision Catheter Kit 8784 Ascenda Intrathecal Catheter (74cm spinal segment revision kit); Revision Catheter Kit 8785 Ascenda Accessory Kit. These changes impact the packaging labels associated with the following labels: Model 8780 Implant Manual; Model 8781 Implant Manual; Model 8782 Implant Manual; Model 8784 Implant Manual; Model 8780 Package Label; Model 8781 Package Label; Model 8782 Package Label; Model 8784 Package Label; Model 8785 Package Label.
P870076/S023	09/23/2016	R - Real-Time Proc	FALOPE-RING BAND CONTRACEPTIVE TUBAL OCCLUSION SYSTEM	GYRUS ACMI, INC.	Approval for a change in the material used to thermoform the tray and tray insert from Verex 5400, to Polyethylene Terephthalate Glycol (PETG).

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P880047/S023	09/20/2016	S - Special CBE	GYNECARE INTERCEED ABSORBABLE ADHESION BARRIER	ETHICON, INC.	Approval for the addition of second sensor on the band sealing equipment that seals the open side of the foil pouch of the SURGICEL Family of Absorbable Hemostats and GYNECARE INTERCEED Absorbable Adhesion Barrier products manufactured at Ethicon, Sarl.
P890003/S358	09/06/2016	R - Real-Time Proc	ELITE, ELITE II, MINUET, PREVA, PREVA D, PRODIGY, SYNERGYST II, THERA, THERA-I, ANALYZER, VITATRON LEGACY, VITATRON LEGACY II, REVEAL INSERTABLE LOOP RECORDER SOFTWARE, REVEAL LINQ	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for enhancements to the Medtronic Model SW028 Baseline Operating System Software (BOSS) as well as the Vitatron Model VSH04 Desktop Application software running on the CareLink Encore 29901 Programmer.
P890003/S361	09/12/2016	R - Real-Time Proc	MEDTRONIC EXPRESS MONITOR	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for an iOS version of the Carelink Express mobile app.
P890017/S018	09/28/2016	Y - 135 Review Tra	PALMAZ BALLOON EXPANDABLE STENT	CORDIS CORP.	Approval for a change to the packaging materials for the PALMAZ Balloon-Expandable Stent.
P890023/S025	09/22/2016	O - Normal 180 Day	SOFMED TORIC WEEKLIES	THE COOPER COMPANIES	Approval for the addition of a new private label brand name Sofmed Toric Weeklies.
P910018/S020	09/23/2016	N - Normal 180 Day	LIPOSORBER® LA-15 SYSTEM	KANEKA PHARMA AMERICA CORP.	Approval for a modification of the indications for use of the system.
P910023/S373	09/08/2016	R - Real-Time Proc	ELLIPSE FAMILY OF ICDS	ST. JUDE MEDICAL	Approval for changes to the patient notifier assembly.
P910023/S375	09/06/2016	R - Real-Time Proc	FORTIFY ASSURA VR, FORTIFY ASSURA DR	ST. JUDE MEDICAL	Approval for a minor design modification to the vibratory patient notifier.
P910073/S138	09/29/2016	N - Normal 180 Day	ENDOTAK RELIANCE 4-SITE, DEFIBRILLATION LEAD FAMILY ,ACTIVE FIXATION MODELS (NEW): 0272, 0273. PASSIVE FIXATION MODELS (NEW): 0262, 0263	BOSTON SCIENTIFIC	Approval for a line extension for silicone backfilled coils.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P920015/S177	09/07/2016	N - Normal 180 Day	SPRINT QUATTRO SECURE S MRI SURESCAN LEAD MODEL 6935M, SPRINT QUATTRO SECURE MRI SURESCAN LEAD MODEL 6947M	MEDTRONIC INC.	Approval for 1.5 and 3T MR-conditional labeling for MRI SureScan lead Models 4074, 4574, and 4076 when used with currently approved SureScan MR-conditional devices.
P920046/S009	09/09/2016	N - Normal 180 Day	FILSHIE CLIP (MARK VI) SYSTEM	FEMCARE LTD.	Approval for changing MR Conditional to 3T.
P930029/S055	09/29/2016	R - Real-Time Proc	RF ENHANCR II	MEDTRONIC INC.	Approval for molding and pad printing changes to the RF Enhancr II handle.
P930039/S149	09/07/2016	N - Normal 180 Day	CAPSUREFIX MRI 4076,CAPSUREFIX NOVUS MRI 5076, CAPSUREFIX MRI SURESCAN 5086MRI LEAD MODELS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for 1.5 and 3T MR-conditional labeling for MRI SureScan lead Models 4074, 4574, and 4076 when used with currently approved SureScan MR-conditional devices.
P940016/S021	09/09/2016	R - Real-Time Proc	HEPARIN-INDUCED EXTRACORPOREAL LDL PRECIPITATION (H.E.L.P.) FUTURA APHERESIS SYSTEM	B. BRAUN AVITUM AG	Approval for changes in primary packaging of the H.E.L.P. Futura Set and individually packed filters.
P950029/S111	09/27/2016	R - Real-Time Proc	REPLY SR, REPLY DR, ESPRIT SR, ESPRIT DR PACEMAKERS	SORIN GROUP- CRM	Approval for Remote Monitoring System software version 3.7.
P960013/S083	09/26/2016	R - Real-Time Proc	TENDRIL ST, STS AND OPTISENSE LV LEADS	PACESETTER, INC.	Approval for changes to the front seal dimensions of the Tendril ST, STS and OptiSense LV leads.
P970012/S099	09/06/2016	R - Real-Time Proc	KAPPA 400	MEDTRONIC INC.	Approval for enhancements to the Medtronic Model SW028 Baseline Operating System Software (BOSS) as well as the Vitatron Model VSH04 Desktop Application software running on the CareLink Encore 29901 Programmer.
P970051/S143	09/01/2016	N - Normal 180 Day	NUCLEUS 24 COCHLEAR IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for a new CochlearTM CP950 Kanso sound processor, which is an external component of both the Nucleus 24 Cochlear Implant System and the Nucleus Hybrid L24 Implant System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980016/S579	09/07/2016	N - Normal 180 Day	EVERA MRI XT DR SURESCAN MODEL DDMB1D4, EVERA MRI XT VR SURESCAN MODEL DVMB1D4,EVERA MRI S DR SURESCAN MODEL DDMC3D4, EVERA MRI S VR SURESCAN MODEL DVMC3D4 IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICDS)	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for 1.5 and 3T MR-conditional labeling for MRI SureScan lead Models 4074, 4574, and 4076 when used with currently approved SureScan MR-conditional devices.
P980016/S593	09/06/2016	R - Real-Time Proc	ENTRUST, GEM,GEM II, GEM III, INTRINSIC, MARQUIS, MAXIMO, MAXIMO II, ONYX, PROTECTA DF4, PROTECTA, PROTECTA XT DF4 PROTECTA XT, SECURA DF4, SECURA, VIRTUOSO, VIRTUOSO II, EVERA S DR, RIGHT VENTRICULAR LEAD INTEGRITY ALERT, EVERA S VR, XT DR, XT VR, EVERA MRI, VISA AF	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for enhancements to the Medtronic Model SW028 Baseline Operating System Software (BOSS) as well as the Vitatron Model VSH04 Desktop Application software running on the CareLink Encore 29901 Programmer.
P980016/S596	09/12/2016	R - Real-Time Proc	EVERA MRI/S DR/S VR/XT DR/XT VR, INTRINSIC 30, MARQUIS VR, MAXIMO II, PROTECTA/PROTECTA VR/XT, SECURA/SECURA DR, VIRTUOSO II DR/VR, VISIA AF MRI VR/AF VR FAMILIES OF ICDS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for an iOS version of the Carelink Express mobile app.
P980035/S464	09/07/2016	N - Normal 180 Day	ADVISA MRI DR & SR SURESCAN IMPLANTABLE PULSE GENERATORS MODELS A2DR01 & A3SR01	MEDTRONIC INC.	Approval for 1.5 and 3T MR-conditional labeling for MRI SureScan lead Models 4074, 4574, and 4076 when used with currently approved SureScan MR-conditional devices.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980035/S469	09/06/2016	R - Real-Time Proc	ADAPTA, ADVISA, AT500, ENPULSE, ENRHYTHM, KAPPA 600, 650, 700, 800, 900; RELIA, SENSIA, SIGMA, VERSA	MEDTRONIC INC.	Approval for enhancements to the Medtronic Model SW028 Baseline Operating System Software (BOSS) as well as the Vitatron Model VSH04 Desktop Application software running on the CareLink Encore 29901 Programmer.
P980035/S470	09/22/2016	N - Normal 180 Day	ADAPTA, VERSA, SENSIA IPG AND RELIA IPG	MEDTRONIC INC.	Approval for an alternate Hall sensor integrated circuit used in the Adapta, Versa, Sensia, and Relia families of IPG devices.
P980035/S471	09/12/2016	R - Real-Time Proc	ADAPTA/VERSA/SENSIA, ADVISA DR/DR MRI/SR MRI, ENPULSE E1/E2, KAPPA DR (KAPPA 700/600, 900/800)/ VDD (KAPPA 700) FAMILIES OF IPGS	MEDTRONIC INC.	Approval for an iOS version of the Carelink Express mobile app.
P980049/S117	09/27/2016	R - Real-Time Proc	PLATINUM VR/DR ICDS,PARADYM RF VR/ RF DR CRT-DS, INTENSIA VR, INTENSIA DR	SORIN GROUP- CRM	Approval for Remote Monitoring System software version 3.7.
P980049/S119	09/07/2016	R - Real-Time Proc	PLATINUM VR AND DR IMPLANTABLE CARDIOVERTER DEFIBRILLATOR ICD'S	SORIN GROUP- CRM	Approval for Platinium embedded software version 2.4.2.
P990001/S122	09/06/2016	R - Real-Time Proc	DIVA FAMILY(INCLUDES DIAMOND II, RUBY II, TOPAZ II, JADE II, VITA DDDR, VITA DDD AND VITA VVIR) DEMA FAMILY, SELECTION AFM, C-SERIES, T-SERIES	MEDTRONIC INC.	Approval for enhancements to the Medtronic Model SW028 Baseline Operating System Software (BOSS) as well as the Vitatron Model VSH04 Desktop Application software running on the CareLink Encore 29901 Programmer.
P990009/S043	09/14/2016	S - Special CBE	FLOSEAL HEMOSTATIC MATRIX	BAXTER HEALTHCARE CORP.	Approval for labeling changes to enhance the safety of your device, including removal of the phrase spurting from bleeding types for which use of the device is described as effective in the warnings section of the labeling.
P990023/S016	09/09/2016	N - Normal 180 Day	CELLUGEL(R) OPHTHALMIC VISCOSURGICAL DEVICE	ALCON LABORATORIES	Approval to replace the current product release intravitreal test with the inflammatory release assay (IRA) product release test.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P000025/S084	09/15/2016	P - Panel Track	MED-EL COCHLEAR IMPLANT SYSTEM	MED-EL CORP.	Approval for expanding the indications to include the Electro-acoustic Stimulation (EAS) system that is intended to provide electrical stimulation to the mid- to high-frequency region of the cochlea and acoustic amplification to the low-frequency regions, for candidates with residual low frequency hearing sensitivity. The MED-EL EAS System is indicated for partially deaf individuals aged 18 years and older who have residual hearing sensitivity in the low frequencies sloping to a severe/profound sensorineural hearing loss in the mid to high frequencies, and who obtain minimal benefit from conventional acoustic amplification. Typical preoperative hearing of candidates ranges from normal hearing to moderate sensorineural hearing loss in the low frequencies (thresholds no poorer than 65 dB HL up to and including 500 Hz) with severe to profound mid- to high-frequency hearing loss (no better than 70 dB HL at 2000 Hz and above) in the ear to be implanted. For the non-implanted ear, thresholds may be worse than the criteria for the implanted ear, but may not be better. The CNC word recognition score in quiet in the best-aided condition will be 60% or less, in the ear to be implanted and in the contralateral ear. Prospective candidates should go through a suitable hearing aid trial, unless already appropriately fit with hearing aids.
P000054/S044	09/16/2016	N - Normal 180 Day	INFUSE BONE GRAFT	MEDTRONIC SOFAMOR DANEK USA, INC.	Approval for increasing the size of the bioreactor used to manufacture rhBMP-2 from 6000 L to 12,000 L at the Pfizer Andover, MA Facility.
P000058/S060	09/16/2016	N - Normal 180 Day	INFUSE BONE GRAFT/ MEDTRONIC INTERBODY FUSION DEVICE	MEDTRONIC SOFAMOR DANEK USA, INC.	Approval for increasing the size of the bioreactor used to manufacture rhBMP-2 from 6000 L to 12,000 L at the Pfizer Andover, MA Facility.
P010014/S055	09/01/2016	S - Special CBE	OXFORD PARTIAL KNEE SYSTEM	BIOMET MANUFACTURING CORP.	Approval for the addition of a radiographic assessment decision aid to supplement the patient selection criteria provided in the approved surgical technique for the Oxford Partial Knee System.
P010015/S304	09/06/2016	R - Real-Time Proc	CONSULTA CRT-P, INSYNC, INSYNC III, SYNCRA CRT-P, VIVA CRT-P	MEDTRONIC INC.	Approval for enhancements to the Medtronic Model SW028 Baseline Operating System Software (BOSS) as well as the Vitatron Model VSH04 Desktop Application software running on the CareLink Encore 29901 Programmer.
P010015/S305	09/12/2016	R - Real-Time Proc	CONSULTA, SYNCRA, AND VIVA CRT-PS	MEDTRONIC INC.	Approval for an iOS version of the Carelink Express mobile app.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010031/S540	09/07/2016	N - Normal 180 Day	AMPLIA MRI SURESCAN MODEL DTMB1D4, AMPLIA MRI QUAD SURESCAN MODEL DTMB1QQ, COMPIA MRI SURESCAN MODEL DTMC1D4, COMPIA MRI QUAD SURESCAN MODEL DTMC1QQ IMPLANTABLE CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATION (CRT-DS) DEVICES	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for 1.5 and 3T MR-conditional labeling for MRI SureScan lead Models 4074, 4574, and 4076 when used with currently approved SureScan MR-conditional devices.
P010031/S554	09/06/2016	R - Real-Time Proc	CONCERTO, RIGHT VENTRICULAR LEAD INTEGRITY ALERT, CONCERTO II CRT-D. CONSULTA CRT-D, INSYNC II MARQUIS, II PROTECT, III MARQUIS, INSYNC MAXIMO INSYNC SENTRY, MAXIMO II CRT-D, DF4; PROTECTA CRT-D, DF4, XT CRT-D, XT DF4; BRAVA CRT-D, VIVA S CRT-D, XT CRT-D, CLARIA MRI QUAD CRT-D; AMPLIA MRI QUAD CRT-D;COMPIA MRI QUAD CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for enhancements to the Medtronic Model SW028 Baseline Operating System Software (BOSS) as well as the Vitatron Model VSH04 Desktop Application software running on the CareLink Encore 29901 Programmer.
P010031/S557	09/12/2016	R - Real-Time Proc	AMPLIA MRI/MRI QUAD, BRAVA/BRAVA QUAD, COMPIA MRI/MRI QUAD, CONCERTO/CONCERT II, CONSULTA, MAXIMO II, PROTECTA/PROTECTA XT, VIVA QUAD S/QUAD XT, VIVA S/XT FAMILIES OF CRT-DS	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Approval for an iOS version of the Carelink Express mobile app.
P010032/S097	09/19/2016	N - Normal 180 Day	INFINITY NEUROSTIMULATION SYSTEM	ST. JUDE MEDICAL	Approval for the Clinician Programmer App (Version 3.1) Model 3874, Programmer App (Version 3.1) Model 3875, and the Infinity Neurostimulation System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010032/S120	09/15/2016	R - Real-Time Proc	GENESIS AND EON FAMILY NEUROSTIMULATION (IPG) SYSTEMS	ST. JUDE MEDICAL	Approval for a new optional accessory, the Lead and Extension Insertion Tool (Model 1803), for use with approved SJM Implantable Pulse Generators (IPGs) and compatible leads, extensions, and adapters.
P020004/S136	09/22/2016	R - Real-Time Proc	GORE EXCLUDER AAA ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Approval for an alternate colorant to be used for components of the AAA Device C3 Delivery System and IBE Device Delivery System
P020011/S009	09/19/2016	Y - 135 Review Tra	APTIMA HCV RNA QUALITATIVE ASSAY	GEN-PROBE	Approval of a new supplier for a critical raw material.
P020014/S047	09/29/2016	O - Normal 180 Day	ESSURE SYSTEM FOR PERMANENT BIRTH CONTROL (MODEL ESS305)	BAYER PHARMA AG	Approval of changes to the post-approval protocol.
P020056/S034	09/22/2016	R - Real-Time Proc	NATRELLE SILICONE-FILLED BREAST IMPLANTS	ALLERGAN	Approval for Inspira Cohesive Silicone-Filled Breast Implants filled with highly cohesive silicone gel.
P030004/S011	09/20/2016	R - Real-Time Proc	ONYX LIQUID EMBOLIC SYSTEM	EV3 NEUROVASCULAR	Approval for minor packaging, sterilization and labeling changes to the Onyx 18 and 34 Kits.
P030027/S009	09/01/2016	O - Normal 180 Day	CERAMIC TRANSCEND HIP ARTICULATION	MICROPORT ORTHOPEDICS INC.	Approval for a manufacturing site located at Sterigenics US LLC, 1700 College Blvd, West Memphis, Arizona, 72301.
P030054/S307	09/06/2016	R - Real-Time Proc	UNIFY ASSURA, QUADRA ASSURA	ST. JUDE MEDICAL	Approval for a minor design modification to the vibratory patient notifier.
P030056/S009	09/09/2016	N - Normal 180 Day	ADVIA CENTAUR® HCV ASSAY	SIEMENS HEALTHCARE DIAGNOSTICS	Approval for the migration of the ADVIA Centaur® HCV (aHCV) to the ADVIA Centaur® XPT system.
P040037/S091	09/22/2016	O - Normal 180 Day	GORE VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Approval for a Post-Approval study labeling update to include the final study results for the extended follow-up 25cm Viabahn Endoprosthesis study.
P040044/S068	09/06/2016	O - Normal 180 Day	MYNXGRIP VASCULAR CLOSURE DEVICE (5F, 6F/7F)	ACCESS CLOSURE, INC.	Approval for a manufacturing site located at 9020 Activity Road, Suite D, San Diego, California, 92126 for the sterilization of the Mynx Grip Vascular Closure Device (5F/6F/7F) and Mynx Ace Vascular Closure Device (5F/6F/7F).
P050018/S022	09/06/2016	R - Real-Time Proc	ANGIOSCULPT(R) PTCA SCORING BALLOON CATHETER	SPECTRANETICS CORP.	Approval for a non-patient contacting material change for a component of the AngioSculpt PTCA Scoring Balloon Catheter.
P050050/S008	09/01/2016	O - Normal 180 Day	SCANDINAVIAN TOTAL ANKLE REPLACEMENT SYSTEM (S.T.A.R.ANKLE)	STRYKER CORPORATION	Approval of changes to the post-approval study protocol.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P050050/S010	09/28/2016	R - Real-Time Proc	SCANDINAVIAN TOTAL ANKLE REPLACEMENT SYSTEM (S.T.A.R. ANKLE)	STRYKER CORPORATIO N	Approval for the use of three specific saw blades in the S.T.A.R. ankle surgical technique.
P050053/S035	09/16/2016	N - Normal 180 Day	INFUSE BONE GRAFT	MEDTRONIC INC.	Approval for increasing the size of the bioreactor used to manufacture rhBMP-2 from 6000 L to 12,000 L at the Pfizer Andover, Massachusetts facility.
P060027/S083	09/27/2016	R - Real-Time Proc	PLATINIUM, PARADYM RF, RF VR, RF DR, INTENSIA CRT-DS	SORIN GROUP CRM USA, INC	Approval for Remote Monitoring System software version 3.7.
P060027/S084	09/07/2016	R - Real-Time Proc	PLATINUM CARDIAC RESYNCHRONIZATION THERAPY DEFBRILLATOR CRT'S	SORIN GROUP CRM USA, INC	Approval for Platinium embedded software version 2.4.2.
P060038/S029	09/23/2016	Y - 135 Review Tra	MITROFLOW AORTIC PERICARDIAL HEART VALVE	LIVANOVA CANADA CORP.	Approval for the addition of a new bovine tissue supplier.
P060040/S060	09/29/2016	N - Normal 180 Day	HEARTMATE II LEFT VENTRICULAR ASSIST SYSTEM (LVAS)	THORATEC CORP.	Approval for mechanical and marking modifications to the System Controller and Percutaneous Cable.
P080006/S090	09/07/2016	N - Normal 180 Day	ATTAIN ABILITY MRI SURESSCAN LEAD 4196, ATTAIN ABILITY PLUS MRI SURESCAN LEAD MODEL 4296, ATTAIN ABILITY STRAIGHT MRI SURESCAN LEAD MODEL 4396,ATTAIN ABILITY PERFORMA MRI SURESCAN LEAD MODEL 4298, ATTAIN ABILITY PERFORMA STRAIGHT MRI SURESCAN LEAD MODEL 4398, ATTAIN ABILITY PERFORMA S MRI SURESCAN LEAD MODEL 4598	MEDTRONIC INC.	Approval for 1.5 and 3T MR-conditional labeling for MRI SureScan lead Models 4074, 4574, and 4076 when used with currently approved SureScan MR-conditional devices.
P080020/S020	09/27/2016	P - Panel Track	GEL-ONE	SEIKAGAKU CORP.	Approval for Gel-One. The device is indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to non-pharmacologic therapy, non-steroidal anti-inflammatory drugs (NSAIDs) or analgesics, e.g., acetaminophen.
P090013/S221	09/07/2016	N - Normal 180 Day	REVO MRI SURESCAN IPG AND PACING SYSTEM RVDR01	MEDTRONIC, INC	Approval for 1.5 and 3T MR-conditional labeling for MRI SureScan lead Models 4074, 4574, and 4076 when used with currently approved SureScan MR-conditional devices.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P090013/S230	09/06/2016	R - Real-Time Proc	REVO MRI, ENRHYTHM MRI	MEDTRONIC, INC	Approval for enhancements to the Medtronic Model SW028 Baseline Operating System Software (BOSS) as well as the Vitatron Model VSH04 Desktop Application software running on the CareLink Encore 29901 Programmer.
P090013/S231	09/12/2016	R - Real-Time Proc	REVO MRI SURESCAN IPG	MEDTRONIC, INC	Approval for an iOS version of the Carelink Express mobile app.
P100024/S010	09/27/2016	R - Real-Time Proc	HER2 CISH PHARMDX KIT	DAKO DENMARK A/S	Approval for the DakoLink software version 4.1 update for the HER2 CISH pharmDx Kit
P100026/S036	09/02/2016	N - Normal 180 Day	NEUROPACE RNS SYSTEM	NEUROPACE INC	Approval for an update to the Patient Data Management System (PDMS).
P100042/S008	09/19/2016	Y - 135 Review Tra	APTIMA HPV ASSAY	GEN-PROBE INCORPORATED	Approval of a new supplier for a critical raw material.
P110010/S123	09/09/2016	O - Normal 180 Day	PROMUS(ELEMENT PLUS/ PREMIER) EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Approval for an update to the post approval study labeling.
P110033/S021	09/12/2016	O - Normal 180 Day	JUVEDERM VOLUMA XC	ALLERGAN	Approval for the labeling for Juvederm Voluma XC has been revised as follows: 1) to include the results of the completed post-approval study; 2) to include revisions to the postmarket surveillance summary; and 3) to include minor revisions intended to harmonize the directions with those of other Juvederm products.
P110033/S023	09/01/2016	R - Real-Time Proc	JUVEDERM VOLBELLA XC	ALLERGAN	Approval for the addition of a 0.55 mL-filled syringe configuration in the same 1 mL COC syringe for Juvederm VOLBELLA XC.
P110038/S012	09/19/2016	R - Real-Time Proc	RELAY THORACIC STENT-GRAFT WITH PLUS DELIVERY SYSTEM	BOLTON MEDICAL, INC.	Approval for an alternate material and joining method for the delivery system secondary sheath (also referred to as the constraining sleeve).
P120005/S049	09/16/2016	R - Real-Time Proc	DEXCOM G5 MOBILE CONTIUOUS GLUCOSE MONITORING SYSTEM	DEXCOM, INC.	Approval for updates to the G5 Mobile iOS App Software and G5 Mobile Transmitter Firmware for Dexcom¿s G5 Mobile Continuous Glucose Monitoring System. The App is being modified to: backfill data from the CGM if there are data gaps within the last 3 hours; include mute override settings, which allow users to hear alerts critical to safe and effective use of the device even when their smart device is muted or turned to a very low volume; and to correct software anomalies. The Transmitter Firmware is being modified to: transmit data for backfill in the App; improve efficiency of battery usage on the transmitter; expand transmitter database logging to include additional information; support internal engineering efforts; and to correct software anomalies.
P120007/S006	09/19/2016	Y - 135 Review Tra	APTIMA HPV 16 18/45 GENOTYPE ASSAY	GEN-PROBE INCORPORATED	Approval for a change of a raw material supplier.
P130006/S030	09/22/2016	O - Normal 180 Day	GORE VIABAHN ENDOPROSTHESIS AND ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Approval for a Post-Approval study labeling update to include the final study results for the extended follow-up 25cm Viabahn Endoprosthesis study.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130009/S053	09/20/2016	O - Normal 180 Day	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE AND ACCESSORIES	EDWARDS LIFESCIENCES, LLC.	Approval of the post-approval study protocol.
P130011/S005	09/23/2016	Y - 135 Review Tra	SOLO SMART STENTLESS HEART VALVE	LIVANOVA CANADA CORP.	Approval for the addition of a new bovine tissue supplier.
P130016/S016	09/01/2016	N - Normal 180 Day	NUCLEUS HYBRID L24 IMPLANT SYSTEM	COCHLEAR AMERICAS	Approval for a new CochlearTM CP950 Kanso sound processor, which is an external component of both the Nucleus 24 Cochlear Implant System and the Nucleus Hybrid L24 Implant System.
P130030/S023	09/27/2016	Y - 135 Review Tra	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL AND OVER THE WIRE	BOSTON SCIENTIFIC CORP.	Approval to sterilize the REBEL and Blazer products with the BSC2000-2 EO Sterilization Cycle at Synergy Health Costa Rica.
P140009/S001	09/19/2016	N - Normal 180 Day	INFINITY NEUROSTIMULATION SYSTEM	ST. JUDE MEDICAL NEUROMODULATION	Approval for the Clinician Programmer App (Version 3.1) Model 3874, Programmer App (Version 3.1) Model 3875, and the Infinity Neurostimulation System.
P140009/S017	09/15/2016	R - Real-Time Proc	BRIO NEUROSTIMULATION SYSTEM	ST. JUDE MEDICAL NEUROMODULATION	Approval for a new optional accessory, the Lead and Extension Insertion Tool (model 1803), for use with approved SJM Implantable Pulse Generators (IPGs) and compatible leads, extensions, and adapters.
P140010/S015	09/07/2016	P - Panel Track	IN PACT ADMIRAL PACLITAXEL-ELUTING PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY BALLOON CATHETER	MEDTRONIC INC.	Approval for the IN.PACT Admiral Paclitaxel-coated PTA Balloon Catheter. The device is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, of de novo, restenotic, or in-stent restenotic lesions with lengths up to 180 mm in superficial femoral or popliteal arteries with reference vessel diameters of 4-7 mm.
P140013/S003	09/21/2016	R - Real-Time Proc	MINERVA ENDOMETRIAL ABLATION SYSTEM	MINERVA SURGICAL	Approval for the addition of two gas shutoff solenoid valves and the implementation of a thermally bonded manifold module.
P140017/S004	09/12/2016	N - Normal 180 Day	ENSEMBLE II TRANSCATHETER VALVE DELIVERY SYSTEM	MEDTRONIC INC.	Approval for a product line extension to the Ensemble Transcatheter Valve Delivery System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140023/S004	09/24/2016	N - Normal 180 Day	COBAS KRAS MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	The cobas® KRAS Mutation Test, for use with the cobas® 4800 System, is a real-time PCR test for the detection of mutations in codons 12, 13 and 61 of the KRAS gene in DNA derived from formalin-fixed paraffin-embedded human colorectal cancer (CRC) tumor tissue. The test is intended to be used as an aid in the identification of CRC patients who should not be treated with Erbitux® (cetuximab) or with Vectibix® (panitumumab) when KRAS Codon 12 or 13 mutation is detected. Safety and efficacy of Erbitux® (cetuximab) or Vectibix® (panitumumab) have not been established in patients whose tumors have Codon 61 mutation. Specimens are processed using the cobas® DNA Sample Preparation Kit for manual sample preparation and the cobas z 480 analyzer for automated amplification and detection.
P150005/S004	09/27/2016	Y - 135 Review Tra	BLAZER OPEN-IRRIGATED ABLATION CATHETER	BOSTON SCIENTIFIC CORP.	Approval to sterilize the REBEL and Blazer products with the BSC2000-2 EO Sterilization Cycle at Synergy Health Costa Rica.
P150011/S005	09/23/2016	Y - 135 Review Tra	PERCEVAL SUTURELESS HEART VALVE	LIVANOVA CANADA CORP.	Approval for the addition of a new bovine tissue supplier.
P150013/S002	09/23/2016	R - Real-Time Proc	PD-L1 IHC 22C3 PHARMDX	DAKO NORTH AMERICA, INC.	Approval for addition of the Dako PT Link PT200 programmable water bath for pre-treatment of tissue sections when using PD-L1 IHC 22C3 pharmDx.
P150017/S002	09/29/2016	O - Normal 180 Day	CARTIVA SYNTHETIC CARTILAGE IMPLANT DEVICE	CARTIVA, INC	Approval of the protocol for the ODE Lead PMA Post-Approval Study protocol.
P150024/S001	09/01/2016	S - Special CBE	ASPIREASSIST	ASPIRE BARIATRICS INC	Approval of the addition of a lot number to the Skin Port and Connector.
P150024/S003	09/13/2016	S - Special CBE	ASPIREASSIST	ASPIRE BARIATRICS INC	Approval for the addition of a Skin-Port manufacturing in-process leak test.
P150038/S001	09/29/2016	O - Normal 180 Day	EXABLATE NEURO THALAMOTOMY	INSIGHTEC	Approval of the protocol for the ODE Lead PMA Post-Approval Study protocol.

Total: 98

30-Day Notice

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
N12159/S040	09/28/2016	X - 30-Day Notice	SURGICEL FAMILY OF ABSORBABLE HEMOSTAT	ETHICON, INC.	Implementation of a new piece of automatic cutting equipment for the SURGICEL Original, Nu-Knit and Fibrillar Absorbable Hemostat devices.
N970003/S193	09/13/2016	X - 30-Day Notice	INGENIO 2 PACEMAKERS, ALTURA 2, ESSENTIO, PROPONENT, ACCOLADE MODEL'S	BOSTON SCIENTIFIC CORP.	Changes to visual inspection criteria for cosmetic defects.
N970003/S194	09/29/2016	X - 30-Day Notice	ADVANTIO; INGENIO; VITALIO; FORMIO; ESSENTIO; PROPONENT; ACCOLADE; ALTRUA 2 PACEMAKERS.	BOSTON SCIENTIFIC CORP.	Addition of a software interface between the traceability system software and the braze oven equipment for the feedthru component braze process.
P810006/S073	09/15/2016	X - 30-Day Notice	COLLASTAT / INSTAT ABSORBABLE COLLAGEN HEMOSTATIC AGENTS	INTEGRA LIFESCIENCES CORPORATION	Replacement of a portion of the water deionization system located in the Collagen Manufacturing Center at 105 Morgan Lane, Plainsboro, New Jersey, 08536.
P820003/S136	09/29/2016	X - 30-Day Notice	PATIENT CABLE	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of a user interface to automate interaction with label printing software during packaging and shipping.
P830055/S174	09/07/2016	X - 30-Day Notice	LCS(R) TOTAL KNEE SYSTEM	DEPUY, INC.	Change in dosimetry system from PMMA to Alanine at the subcontractor Synergy Westport sterilization site.
P830055/S175	09/20/2016	X - 30-Day Notice	LCS KNEE SYSTEM	DEPUY, INC.	Addition of a two dimensional (2D) barcode to the PFC Sigma RPF Tibial inserts and changes to the inspection process for the LCS® Total Knee System.
P830061/S132	09/20/2016	X - 30-Day Notice	CAPSURE SENSE LEAD; VITATRON CRYSTALLINE LEAD, ICM09	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Updates to pull test sample sizes and control limits.
P830061/S133	09/21/2016	X - 30-Day Notice	CAPSURE SENSE LEAD MODELS 4074, 4574	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Transfer of the vacuum annealing process to the Medtronic Singapore Operations facility.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P830061/S134	09/28/2016	X - 30-Day Notice	CAPSURE SENSE LEAD; CAPSURE SP NOVUS LEAD; VITATRON CYRSTALLINE LEAD; VITATRON EXCELLENCE PS+ LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Additional supplier for stylet components.
P840001/S340	09/09/2016	X - 30-Day Notice	RESTORE, ITREL, AND SYNERGY SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Relocation of titanium cleaning and annealing processes from Bodycote to Greatbatch Medical.
P840001/S341	09/13/2016	X - 30-Day Notice	RESTORE, ITREL, AND SYNERGY SPINAL CORD STIMULATION SYSTEM AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Addition of an alternate supplier of lead wire components and implementation of an alternate test equipment for that supplier.
P840001/S342	09/14/2016	X - 30-Day Notice	RESTORE, ITREL, AND SYNERGY SPINAL CORD STIMULATION SYSTEMS AND PISCES, SPECIFY, AND VECTRIS SPINAL CORD STIMULATION LEADS	MEDTRONIC NEUROMODULATION	Use of Cell Operating System workstation U-shaped configuration instead of the current use of a clean bench in the Neuromodulation Sterile Packaging manufacturing area at Medtronic Puerto Rico Operation Company (MPROC).
P840062/S057	09/15/2016	X - 30-Day Notice	COLLACOTE(TM) COLLATAPE(R) ABSORBABLE COLLEGAGEN WOUND DRESSINGS	COLLA-TEC, INC.	Replacement of a portion of the water deionization (DI) system, located in the Collagen Manufacturing Center. Integra will replace a portion of the DI system with a new Evoqua IonRight GEN3 system. The change is being made to lower operating expenses, as well as reduce the frequency of service of the system by reducing the frequency at which the vessels are shipped off site for regeneration.
P850010/S072	09/15/2016	X - 30-Day Notice	HELISTAT HELITENE ABSORBABLE COLLAGEN HEMOSTATIC AGENT	INTEGRA LIFESCIENCES CORPORATION	Replacement of a portion of the water deionization (DI) system, located in the Collagen Manufacturing Center. Integra will replace a portion of the DI system with a new Evoqua IonRight GEN3 system. The change is being made to lower operating expenses, as well as reduce the frequency of service of the system by reducing the frequency at which the vessels are shipped off site for regeneration.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P850089/S119	09/28/2016	X - 30-Day Notice	CAPSURE SP NOVUS/ CAPSURE SP Z/CAPSURE Z NOVUS LEADS, VITATRON IMPULSE II LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Additional supplier for stylet components.
P860004/S260	09/09/2016	X - 30-Day Notice	SYNCHROMED INFUSION SYSTEM	MEDTRONIC INC.	Relocation of titanium cleaning and annealing processes from Bodycote to Greatbatch Medical.
P860057/S153	09/19/2016	X - 30-Day Notice	EDWARDS LIFESCIENCES PERIMOUNT AORTIC AND MITRAL BIOPROSTHESES	EDWARDS LIFESCIENCES, LLC.	Implement an additional in-process flow tester at the Singapore facility.
P880047/S024	09/27/2016	X - 30-Day Notice	GYNECARE INTERCEED ABSORBABLE ADHESION BARRIER	ETHICON, INC.	Implementation of a new piece of automatic slitting equipment for the GYNECARE INTERCEED Absorbable Adhesion Barrier.
P880086/S275	09/27/2016	X - 30-Day Notice	ASSURITY, ASSURITY+, ENDURITY, ENDURITY CORE	ST. JUDE MEDICAL, INC.	Implementation of an automated test solution for hybrid assemblies.
P890003/S363	09/28/2016	X - 30-Day Notice	CAPSURE VDD 2 LEAD, VITATRON BRILLIANT S+ VVD LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Additional supplier for stylet components.
P890003/S364	09/29/2016	X - 30-Day Notice	ANALYZER ADAPTORS, CABLE, PATIENT CABLE; ECG CABLE, OUTPUT ADAPTOR	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of a user interface to automate interaction with label printing software during packaging and shipping.
P890055/S065	09/26/2016	X - 30-Day Notice	CODMAN 3000 CONSTANT-FLOW IMPLANTABLE INFUSION PUMP	CODMAN	Use a suture material for the Codman 3000 Implantable Infusion Pump from a supplier that has changed ownership from Sherwood Davis & Geck to Medtronic.
P900033/S056	09/15/2016	X - 30-Day Notice	INTEGRA ARTIFICAL SKIN DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	Replacement of a portion of the water deionization (DI) system, located in the Collagen Manufacturing Center. Integra will replace a portion of the DI system with a new Evoqua IonRight GEN3 system. The change is being made to lower operating expenses, as well as reduce the frequency of service of the system by reducing the frequency at which the vessels are shipped off site for regeneration.
P900033/S057	09/22/2016	X - 30-Day Notice	INTEGRA ARTIFICIAL SKIN DERMAL REGENERATION TEMPLATE	INTEGRA LIFESCIENCES CORP.	New Tyvek heat sealer and sealing parameters.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P900061/S141	09/29/2016	X - 30-Day Notice	PATIENT MAGNET	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of a user interface to automate interaction with label printing software during packaging and shipping.
P920015/S182	09/20/2016	X - 30-Day Notice	SPRINT QUATTRO LEAD; SUBCUTANEOUS LEAD	MEDTRONIC INC.	Updates to pull test sample sizes and control limits.
P920015/S183	09/28/2016	X - 30-Day Notice	SPRINT QUATTRO/ SUBCUTANEOUS/ TRANSVENE CS/SVC LEADS	MEDTRONIC INC.	Additional supplier for stylet components.
P930039/S155	09/01/2016	X - 30-Day Notice	CAPSUREFIX NOVUS LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Update to power and weld settings in the laser welding process.
P930039/S156	09/20/2016	X - 30-Day Notice	CAPSURE FIX NOVUS LEAD; VITATRON CRYSTALLINE ACTIVE; FIXATION LEAD, ICF09, ICQ09B	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Updates to pull test sample sizes and control limits.
P930039/S157	09/21/2016	X - 30-Day Notice	CAPSUREFIX NOVUS LEAD MODEL 4076	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Transfer of the vacuum annealing process to the Medtronic Singapore Operations facility.
P930039/S158	09/28/2016	X - 30-Day Notice	CAPSUREFIX,CAPSUREFIX NOVUS, VITATRON CRYSTALLINE ACTIVE FIXATION LEAD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Additional supplier for stylet components.
P940035/S013	09/08/2016	X - 30-Day Notice	ALERE NMP22 BLADDERCHEK TEST	ALERE SCARBOROUGH, INC	Additional vendor for the goat anti-mouse IgG antibody used in the manufacture of the Alere NMP22® BladderChek® Test procedural control line.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P950005/S062	09/21/2016	X - 30-Day Notice	CELSIUS/DEFLECTABLE TIP ELECTROPHYSIOLOGY CATHETER	CORDIS CORP.	Transfer of the extrusion process for the Proximal Reinforcing Sleeve subcomponent.
P950020/S075	09/27/2016	X - 30-Day Notice	WOLVERINE CORONARY CUTTING BALLOON MONORAIL, OVER-THE WIRE.	BOSTON SCIENTIFIC CORP.	Introduce a new crimping machine for the marker band securement process.
P960009/S261	09/09/2016	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Relocation of titanium cleaning and annealing processes from Bodycote to Greatbatch Medical.
P960009/S262	09/13/2016	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Addition of an alternate supplier of lead wire components and implementation of an alternate test equipment for that supplier.
P960009/S263	09/14/2016	X - 30-Day Notice	ACTIVA DEEP BRAIN STIMULATION THERAPY SYSTEM	MEDTRONIC INC.	Use of Cell Operating System workstation U-shaped configuration instead of the current use of a clean bench in the Neuromodulation Sterile Packaging manufacturing area at Medtronic Puerto Rico Operation Company (MPROC).
P960016/S067	09/08/2016	X - 30-Day Notice	LIVEWIRE TC STEERABLE ELECTROPHYSIOLOGY CATHETER	ST. JUDE MEDICAL	Changes to the environmental specifications and installation of data loggers for environmental monitoring.
P960040/S379	09/13/2016	X - 30-Day Notice	NG3 IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD), ORIGEN, INOGEN, DYNAGEN EL ICD'S; NG2 IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) ORIGEN, INOGEN, DYNAGEN MINI ICD'S	BOSTON SCIENTIFIC	Changes to visual inspection criteria for cosmetic defects.
P960040/S380	09/29/2016	X - 30-Day Notice	ORIGEN; INOGEN; DYNAGEN; PUNCTUA; ENERGEN; INCEPTA ICDS	BOSTON SCIENTIFIC	Addition of a software interface between the traceability system software and the braze oven equipment for the feedthru component braze process.
P970003/S204	09/09/2016	X - 30-Day Notice	ASPIRESR MODEL 106 GENERATOR	CYBERONICS, INC.	Implementation of new electrical testing for the Model 106 Generator used in the VNS Therapy System, with additional minor test software corrections and improvements.
P970004/S224	09/09/2016	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Relocation of titanium cleaning and annealing processes from Bodycote to Greatbatch Medical.
P970004/S226	09/13/2016	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Addition of an alternate supplier of lead wire components and implementation of an alternate test equipment for that supplier.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P970004/S227	09/14/2016	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Use of Cell Operating System workstation U-shaped configuration instead of the current use of a clean bench in the Neuromodulation Sterile Packaging manufacturing area at Medtronic Puerto Rico Operation Company (MPROC).
P980016/S598	09/15/2016	X - 30-Day Notice	EVERA MRI, S DR, S VR, XT DR, XT VR ICD'S; VISIA AM MRI VR ICD AND VISIA AF VR ICD	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Elimination of an in-process pull test performed on the connector subassembly.
P980016/S599	09/29/2016	X - 30-Day Notice	PATIENT MAGNET	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Implementation of a user interface to automate interaction with label printing software during packaging and shipping.
P980024/S015	09/29/2016	X - 30-Day Notice	PATHVYSION HER-2 DNA PROBE KIT	ABBOTT MOLECULAR, INC.	Location change for a component supplier.
P980035/S473	09/01/2016	X - 30-Day Notice	ADAPTA, VERSA, SENSIA IPG ADDR01, ADDR03, ADDR06, ADDRL1, ADDRS1, SEDR01, SESR01, VEDR01, ADD01, SEDRL1, SED01, SES01, ADSR01, ADSR03, ADSR06, ADVDD01; RELIA IPG RED01, REDR01, RES01, RESR01, REVDD01	MEDTRONIC INC.	New annealing vacuum oven used during the manufacture of the battery cases.
P980044/S034	09/13/2016	X - 30-Day Notice	SUPARTZ FX, VISCO-3	SEIKAGAKU CORP.	Change in the VISCO-3 packaging process from manual to a modified automated packaging process.
P980044/S035	09/14/2016	X - 30-Day Notice	SUPARTZ FX VISCO-3	SEIKAGAKU CORP.	Addition of a batch size for the manufacture of SUPARTZ FX and VISCO-3.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P980049/S120	09/20/2016	X - 30-Day Notice	PARADYM VR, DR,PARADYM RF VR, PARADYM RF DR (ZL101), (ZL102),INTENSIA VR, INTENSIA DR,PLATINIUM VR 1210, PLATINIUM VR 1240, PLATINIUM DR 1510, PLATINIUM DR 1540	SORIN GROUP- CRM	Alternate method for the laser welding process.
P980049/S121	09/07/2016	X - 30-Day Notice	PLATINIUM VR 1210,1240 (ICD); PLATINIUM DR 1510, 1540 (ICD)	SORIN GROUP- CRM	Change to the execution sequence for the final functional electrical test and the final functional test for radio frequency.
P980049/S122	09/21/2016	X - 30-Day Notice	ICDS (IMPLANTABLE CARDIOVERTER DEFIBRILLATOR) PLATINIUM VR 1210, 1240; PLATINIUM DR 1510, 1540.	SORIN GROUP- CRM	Alternate manufacturing flow sequence, the addition of new dispensing equipment and an optional step in the manufacturing line for the microelectronic and electronic assembly.
P980050/S106	09/28/2016	X - 30-Day Notice	TRANSVENE CS/SVC LEAD	MEDTRONIC INC.	Additional supplier for stylet components.
P990025/S050	09/21/2016	X - 30-Day Notice	NAVISTAR ELECTROPHYSIOLOGY CATHETER	BIOSENSE WEBSTER, INC.	Transfer of the extrusion process for the Proximal Reinforcing Sleeve subcomponent.
P000037/S047	09/28/2016	X - 30-Day Notice	ON-X PROSTHETIC HEART VALVE AND ON-X ASCENDING AORTIC PROSTHESIS	ON-X LIFE TECHNOLOGIES, INC.	Change to the secondary supplier for the valve holder and holder handle material.
P000058/S062	09/29/2016	X - 30-Day Notice	INFUSE BONE GRAFT; CLYDESDALE SPINAL SYSTEM	MEDTRONIC SOFAMOR DANEK USA, INC.	Alternate inspection methods for the Clydesdale Spinal System 18mm implant; 2) alternate manufacturing equipment for the Clydesdale Spinal System; and 3) the option to perform some manufacturing steps for the Clydesdale Spinal System 22mm implant in-house.
P010003/S025	09/08/2016	X - 30-Day Notice	BIOGLUE SURGICAL ADHESIVE	CRYOLIFE, INC.	Reuse of the BioGlue insulated outer shipper for irradiation.
P010012/S430	09/01/2016	X - 30-Day Notice	ACUITY X4 DRUG COLLAR COMPONENT DWELL TIME	BOSTON SCIENTIFIC CORP.	Extension to the drug collar dwell time.
P010012/S431	09/13/2016	X - 30-Day Notice	NG3 CARDIAC RESYNCHRONIZATION THERAPY-DEFIBRILLATOR (CRT); DYNAGEN. INOGEN, ORIGEN CRT-D & X4 CRT-D	BOSTON SCIENTIFIC CORP.	Changes to visual inspection criteria for cosmetic defects.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P010012/S432	09/29/2016	X - 30-Day Notice	ORIGEN; INOGEN; DYNAGEN; PUNCTUA; ENERGEN; INCEPTA CRT-DS	BOSTON SCIENTIFIC CORP.	Addition of a software interface between the traceability system software and the braze oven equipment for the feedthru component braze process.
P010015/S307	09/28/2016	X - 30-Day Notice	ATTAIN BIPOLAR OTW AND OTW LV LEAD	MEDTRONIC INC.	Additional supplier for stylet components.
P010019/S052	09/08/2016	X - 30-Day Notice	LOTRAFILCON A AND B SOFT CONTACT LENSES FOR DAILY AND EXTENDED WEAR	ALCON LABORATORIES, INC.	Adding an alternate foil lidding material.
P010030/S080	09/01/2016	X - 30-Day Notice	LIFEVEST WEARABLE DEFIBRILLATOR (WCD) 3000, 4000	ZOLL MANUFACTURING CORPORATION	Automated inspection test for therapy electrode assemblies.
P010031/S559	09/15/2016	X - 30-Day Notice	AMPLIA MRI & QUAD CRT-D'S; BRAVA CRT-D & QUAD CRT-D'S; COMPIA MRI CRT-D & QUAD CRT-D; VIVA QUAD S & XT CRT-D; VIVA S CRT-D & VIVA XT CRT-D	MEDTRONIC CARDIAC RHYTHM DISEASE MANAGEMENT	Elimination of an in-process pull test performed on the connector subassembly.
P010068/S052	09/21/2016	X - 30-Day Notice	NAVISTAR DS ELECTROPHYSIOLOGY CATHETER	BIOSENSE WEBSTER, INC.	Transfer of the extrusion process for the Proximal Reinforcing Sleeve subcomponent.
P030005/S141	09/13/2016	X - 30-Day Notice	CARDIAC RESYNCHRONIZATION THERAPY- PACEMAKER (CRT-P); INVIVE & INTUA MODELS; INGENIO 2 CRT-P DEVICES VALITUDE MODEL U 125 & X4 MODEL U128	GUIDANT CORP.	Changes to visual inspection criteria for cosmetic defects.
P030005/S142	09/29/2016	X - 30-Day Notice	VALITUDE; INVIVE CRT-PS	GUIDANT CORP.	Addition of a software interface between the traceability system software and the braze oven equipment for the feedthru component braze process.
P030009/S090	09/28/2016	X - 30-Day Notice	INTEGRITY CORONARY STENT SYSTEM	MEDTRONIC IRELAND	Introducing an upgraded laser ablation machine with integrated automated handling.
P030011/S045	09/21/2016	X - 30-Day Notice	SYNCARDIA TEMPORARY TOTAL ARTIFICIAL HEART (TAH-T) SYSTEM	SYNCARDIA SYSTEMS, INC.	Addition of an alternate supplier for the AC Power Cord.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P030017/S256	09/16/2016	X - 30-Day Notice	PRECISION, PRECISION SPECTRA AND PRECISION NOVI SPINAL CORD STIMULATION(SCS) SYSTEM	BOSTON SCIENTIFIC CORP.	Implement an additional rework process for the Clik Anchor subassembly used in the Precision, Precision Spectra, and Precision Novi Spinal Cord Stimulation Systems.
P030017/S257	09/29/2016	X - 30-Day Notice	PRECISION SPECTRA & NOVI SPINAL CORD STIMULATOR (SCS) SYSTEMS; PRECISION MONTAGE MRI AND PRECISION MONTAGE SPINAL CORD STIMULATOR (SCS) SYSTEMS	BOSTON SCIENTIFIC CORP.	Modify the software used to test the printed circuit board assembly in the Remote Control of your Spinal Cord Stimulation systems.
P030031/S076	09/20/2016	X - 30-Day Notice	THERMOCOOL SMARTTOUCH SF BI-DIRECTIONAL & UNI-DIRECTIONAL NAVIGATION CATHETER	BIOSENSE WEBSTER, INC.	Adding a second source supplier for the tip shell and sensor support component used in the THERMOCOOL SMARTTOUCH SF Navigation Catheters.
P030031/S077	09/21/2016	X - 30-Day Notice	EZ STEER THERMOCOOL NAVIGATION AND THERMOCOOL BI-DIRECTIONAL CATHETER;THERMOCOOL SF/SF NAV BI-DIRECTIONAL AND SF/SF NAV UNI-DIRECTIONAL CATHETER	BIOSENSE WEBSTER, INC.	Transfer of the extrusion process for the Proximal Reinforcing Sleeve subcomponent.
P030035/S149	09/27/2016	X - 30-Day Notice	ALLURE, ALLURE QUADRA, QUADRA ALLURE MP	ST. JUDE MEDICAL, INC.	Implementation of an automated test solution for hybrid assemblies.
P030052/S018	09/29/2016	X - 30-Day Notice	UROVYSION BLADDER CANCER KIT	ABBOTT MOLECULAR	Location change for a component supplier.
P040014/S031	09/08/2016	X - 30-Day Notice	THERAPY ABLATION CATHETERS	IRVINE BIOMEDICAL, INC.	Changes to the environmental specifications and installation of data loggers for environmental monitoring.
P040027/S049	09/21/2016	X - 30-Day Notice	GORE VIATORR TIPS ENDOPROSTHESIS	W. L. GORE & ASSOCIATES, INC.	Implementation of changes to zipper manufacturing which include the use of modified braider machines and a new oven rack and spatula to increase manufacturing capacity.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P040036/S057	09/21/2016	X - 30-Day Notice	THERMOCOOL SMART TOUCH BI-DIRECTIONAL AND ELECTROPHYSIOLOGY	BIOSENSE WEBSTER, INC.	Transfer of the extrusion process for the Proximal Reinforcing Sleeve subcomponent.
P040037/S093	09/21/2016	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS	W.L. GORE & ASSOCIATES,INC	Implementation of changes to zipper manufacturing which include the use of modified braider machines and a new oven rack and spatula to increase manufacturing capacity.
P040042/S036	09/08/2016	X - 30-Day Notice	THERAPY DUAL 8 ABLATION CATHETERS	IRVINE BIOMEDICAL,INC.(IBI)	Changes to the environmental specifications and installation of data loggers for environmental monitoring.
P040044/S074	09/23/2016	X - 30-Day Notice	MYNXGRIP AND MYNX ACE VASCULAR CLOSURE DEVICE	ACCESS CLOSURE, INC.	Qualify a new supplier for the stopcock component.
P050039/S020	09/28/2016	X - 30-Day Notice	NOVATION CERAMIC ARTICULATION HIP SYSTEM	EXACTECH, INC.	Add a dryer to the implant drying process.
P060019/S038	09/08/2016	X - 30-Day Notice	THERAPY COOL PATH ABLATION CATHETERS	IRVINE BIOMEDICAL, INC.	Changes to the environmental specifications and installation of data loggers for environmental monitoring.
P060027/S085	09/20/2016	X - 30-Day Notice	PARADYM CRT-D; PARADYM RF CRT-D (ZL101),(ZL102); INTENSIA CRT-D; PLATINIUM CRT-D 1711,1741.	SORIN GROUP CRM USA, INC	Alternate method for the laser welding process.
P060027/S086	09/07/2016	X - 30-Day Notice	PLATINIUM CRT-D 1711, 1741.	SORIN GROUP CRM USA, INC	Change to the execution sequence for the final functional electrical test and the final functional test for radio frequency.
P060027/S087	09/21/2016	X - 30-Day Notice	CRT-DS (CARDIAC RESYNCHRONIZATION THERAPY DEFIBRILLATOR),PLATINIUM CRT-D 1711, 01741	SORIN GROUP CRM USA, INC	Alternate manufacturing flow sequence, the addition of new dispensing equipment and an optional step in the manufacturing line for the microelectronic and electronic assembly.
P060030/S054	09/13/2016	X - 30-Day Notice	COBAS AMPLIPREP/COBAS TAQMAN HCV TEST	ROCHE MOLECULAR SYSTEMS, INC.	Production scale-up of bulk reagents for the COBAS® AmpliPrep/COBAS® TaqMan® HCV Test.
P060037/S046	09/01/2016	X - 30-Day Notice	NEXGEN LPS-FLEX MOBILE AND LPS-MOBILE BEARING KNEE SYSTEM	ZIMMER, INC.	Addition of Ambatovy Cobalt and Novotroisk Chromium, as second-tier approved raw material suppliers of Zimaloy Cobalt-Chromium-Molybdenum-Alloy Continuous Cast Ignot, used in the manufacture of the femoral components of the NexGen LPS-Flex/LPS Mobile Bearing Knee System.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P060038/S030	09/14/2016	X - 30-Day Notice	MITROFLOW AORTIC PERICARDIAL HEART VALVE	LIVANOVA CANADA CORP.	Upgrade to the Covered Stent Controlled Environment (CSCE) from a lower ISO cleanroom classification to a higher classification as well as the extension of covered stent manufacturing activities to two additional controlled environments.
P060039/S072	09/28/2016	X - 30-Day Notice	ATTAIN STARFIX LEAD	MEDTRONIC INC.	Additional supplier for stylet components.
P070026/S038	09/21/2016	X - 30-Day Notice	CERAMAX CERAMIC TOTAL HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Addition of already approved sterilization site (for other components of the PMA device) for the Pinnacle cups.
P070026/S039	09/21/2016	X - 30-Day Notice	CERAMAX CERAMIC TOTAL HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Addition of already approved sterilization site (for other components of the PMA device) for the Pinnacle cups.
P070026/S042	09/07/2016	X - 30-Day Notice	CERAMAX CERAMIC TOTAL HIP SYSTEM	DEPUY ORTHOPAEDICS, INC.	Change in dosimetry system from PMMA to Alanine at the subcontractor Synergy Westport sterilization site.
P080006/S097	09/20/2016	X - 30-Day Notice	ATTAIN ABILITY LEAD, ATTAIN PERFORMA LEAD	MEDTRONIC INC.	Updates to pull test sample sizes and control limits.
P080006/S098	09/28/2016	X - 30-Day Notice	ATTAIN ABILITY LEAD; ATTAIN PERFORMA LEAD	MEDTRONIC INC.	Additional supplier for stylet components.
P080025/S119	09/09/2016	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Relocation of titanium cleaning and annealing processes from Bodycote to Greatbatch Medical.
P080025/S121	09/13/2016	X - 30-Day Notice	INTERSLIM THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Addition of an alternate supplier of lead wire components and implementation of an alternate test equipment for that supplier.
P080025/S122	09/14/2016	X - 30-Day Notice	INTERSTIM THERAPY SYSTEM	MEDTRONIC NEUROMODULATION	Use of Cell Operating System workstation U-shaped configuration instead of the current use of a clean bench in the Neuromodulation Sterile Packaging manufacturing area at Medtronic Puerto Rico Operation Company (MPROC).
P090013/S233	09/01/2016	X - 30-Day Notice	CAPSUREFIX MRI LEAD	MEDTRONIC, INC	Update to power and weld settings in the laser welding process.
P090013/S234	09/28/2016	X - 30-Day Notice	CAPSUREFIX MRI LEAD	MEDTRONIC, INC	Additional supplier for stylet components.
P090022/S028	09/22/2016	X - 30-Day Notice	LENSTEC SOFTEC HD POSTERIOR CHAMBER INTRAOCULAR LENS	LENSTEC, INC.	Inclusion of one additional steam sterilizer unit for use in the sterilization of the IOLs.
P090022/S029	09/28/2016	X - 30-Day Notice	LENSTEC SOFTEC HD POSTERIOR CHAMBER INTRAOCULAR LENS	LENSTEC, INC.	the addition of a dishwasher for use in the removal of microbial contamination from packaging and device components used in the manufacture of the LENSTEC Softec Posterior Chamber IOLs

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P100042/S011	09/13/2016	X - 30-Day Notice	APTIMA HPV ASSAY	GEN-PROBE INCORPORATED	Addition of a new site for the manufacturing of oligonucleotides.
P100047/S079	09/01/2016	X - 30-Day Notice	HEARTWARE LEFT VENTRICULAR ASSIST SYSTEM	HEARTWARE, INC.	Implementation of an alternate automated option for the Taylor Hobson Profilometer.
P100047/S080	09/07/2016	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST DEVICE SYSTEM	HEARTWARE, INC.	Additional coating chamber at the existing coating supplier for processing components of the HVAD.
P100047/S081	09/12/2016	X - 30-Day Notice	HEARTWARE VENTRICULAR ASSIST SYSTEM	HEARTWARE, INC.	Implementation of an alternate supplier for the polyester yarn used in the manufacturing of the HVAD Sewing Ring.
P100047/S083	09/20/2016	X - 30-Day Notice	HEARTWARE LEFT VENTRICULAR ASSIST DEVICE SYSTEM	HEARTWARE, INC.	Implementation of the Rofin Laser Welding station for the welding of the HVAD Impeller Assembly.
P110010/S133	09/29/2016	X - 30-Day Notice	PROMUS(ELEMENT PLUS/ PREMIER) EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORP.	Replace the black and white camera with a color camera on the Port Bond Inspection Station.
P110012/S011	09/29/2016	X - 30-Day Notice	VYSIS ALK BREAK APART FISH PROBE KIT	ABBOTT MOLECULAR, INC.	Location change for a component supplier.
P110013/S076	09/28/2016	X - 30-Day Notice	RESOLUTE INTEGRITY ZOTAROLIMUS-ELUTING CORONARY STENT SYSTEM	MEDTRONIC VASCULAR	Introducing an upgraded laser ablation machine with integrated automated handling.
P110016/S035	09/08/2016	X - 30-Day Notice	THERAPY COOL PATH DUO/SAFIRE BLU DUO ABLATION CATHETERS	ST. JUDE MEDICAL, INC.	Changes to the environmental specifications and installation of data loggers for environmental monitoring.
P110019/S086	09/27/2016	X - 30-Day Notice	XIENCE XPEDITION & ALPINE EVEROLIMUS ELUTING CORONARY STENT SYSTEM	ABBOTT VASCULAR	Change to the catheter process monitoring system.
P110020/S018	09/20/2016	X - 30-Day Notice	COBAS 4800 BRAF V600 MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Manufacturing scale increase for bulk manufacturing of components.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P110042/S062	09/13/2016	X - 30-Day Notice	EMBLEM S-ICD SYSTEM & EMBLEM MRI S-ICD SYSTEM	BOSTON SCIENTIFIC CORPORATION	Changes to visual inspection criteria for cosmetic defects.
P110042/S063	09/29/2016	X - 30-Day Notice	EMBLEM; EMBLEM MRI (S-ICD)	BOSTON SCIENTIFIC CORPORATION	Addition of a software interface between the traceability system software and the braze oven equipment for the feedthru component braze process.
P110043/S011	09/14/2016	X - 30-Day Notice	OMNILINK ELITE VASCULAR BALLOON-EXPANDABLE STENT SYSTEM	ABBOTT VASCULAR-CARDIAC THERAPIES	Move part of the manufacturing process from one room to another.
P120007/S009	09/13/2016	X - 30-Day Notice	APTIMA HPV 16 18/45 GENOTYPE ASSAY	GEN-PROBE INCORPORATED	Addition of a new site for the manufacturing of oligonucleotides.
P120017/S005	09/20/2016	X - 30-Day Notice	MYOCARDIAL PACING LEAD	MEDTRONIC INC.	Updates to pull test sample sizes and control limits.
P120019/S011	09/20/2016	X - 30-Day Notice	COBAS EGFR MUTATION TEST	ROCHE	Manufacturing scale increase for bulk manufacturing of components.
P120022/S013	09/07/2016	X - 30-Day Notice	THERASCREEN EGFR RGQ PCR KIT	QIAGEN MANCHESTER LTD	Change to the mean Ct specification for the positive control (PC) at the final kit release stage and the target Ct value for the manufacturing adjustment process for the L861Q reaction mix.
P130006/S032	09/21/2016	X - 30-Day Notice	GORE VIABAHN ENDOPROSTHESIS WITH HEPARIN BIOACTIVE SURFACE	W.L. GORE & ASSOCIATES,INC	Implementation of changes to zipper manufacturing which include the use of modified braider machines and a new oven rack and spatula to increase manufacturing capacity.
P130007/S020	09/15/2016	X - 30-Day Notice	ANIMAS VIBE SYSTEM	ANIMAS CORP.	Addition of a second Main Board assembly line for the Animas Vibe Insulin Pump at the supplier. The Vibe Insulin Pump is a component of the Animas Vibe System.
P130009/S064	09/19/2016	X - 30-Day Notice	EDWARDS SAPIEN XT TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Implement an additional in-process flow tester at the Singapore facility.
P130012/S001	09/19/2016	X - 30-Day Notice	MYOPORE SUTURELESS MYOCARDIAL PACING LEAD	GREATBATCH MEDICAL	Implementation of a new silicone mill.
P130012/S002	09/27/2016	X - 30-Day Notice	MYOPORE SUTURELESS MYOCARDIAL PACING LEAD	GREATBATCH MEDICAL	Use of a new anode plate former.
P130019/S010	09/20/2016	X - 30-Day Notice	MAESTRO RECHARGEABLE SYSTEM	ENTEROMEDICS INC.	Material change for the flux used during in-process rework, updated inspection steps, and clarified process instructions for the Model 2002 Rechargeable Neuroregulator.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P130026/S022	09/08/2016	X - 30-Day Notice	TACTICATH QUARTZ CATHETER AND TACTISYS QUARTZ EQUIPMENT	ST. JUDE MEDICAL	Changes to the environmental specifications and installation of data loggers for environmental monitoring.
P130030/S030	09/27/2016	X - 30-Day Notice	REBEL PLATINUM CHROMIUM CORONARY STENT SYSTEM MONORAIL AND OVER THE WIRE	BOSTON SCIENTIFIC CORP.	Introduce a new crimping machine for the marker band securement process.
P140015/S013	09/01/2016	X - 30-Day Notice	T:SLIM G4 INSULIN PUMP WITH DEXCOM G4 PLATINUM CGM	TANDEM DIABETES CARE, INC.	Alternative endotoxin test for the t:slim G4 Insulin Pump and to conduct the test in-house at Tandem Diabetes Care, Inc. The t:slim G4 Insulin Pump is a component of the t:slim G4 Insulin Pump with Dexcom G4 Platinum CGM System.
P140015/S014	09/08/2016	X - 30-Day Notice	T:SLIM G4 INSULIN PUMP WITH DEXCOM G4 PLATINUM CGM	TANDEM DIABETES CARE, INC.	Implementation of process improvements to the manufacturing and testing of the cartridge for the t:slim G4 Insulin Pump. The t:slim G4 Insulin Pump is a component of the T:Slim G4 Insulin Pump with Dexcom G4 Platinum CGM.
P140015/S015	09/23/2016	X - 30-Day Notice	T:SLIM G4 INSULIN PUMP WITH DEXCOM G4 PLATINUM CGM	TANDEM DIABETES CARE, INC.	Change testing software for the t:slim G4 Insulin Pump and to remove one upper limit acceptance criterion for the software test at the Tandem Diabetes Care manufacturing plant in San Diego, CA. The t:slim G4 Insulin Pump is a component of the Dexcom G4 Platinum CGM System.
P140023/S007	09/20/2016	X - 30-Day Notice	COBAS KRAS MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Manufacturing scale increase for bulk manufacturing of components.
P140028/S016	09/02/2016	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATION	Modifications to an in-process control.
P140028/S017	09/12/2016	X - 30-Day Notice	INNOVA (TM) VASCULAR SELF-EXPANDING STENT WITH DELIVERY SYSTEM	BOSTON SCIENTIFIC CORPORATION	Changes to stent machining parameters.
P140028/S018	09/16/2016	X - 30-Day Notice	INNOVA VASCULAR SELF-EXPANDING STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Updated equipment for the stent component manufacturing.
P140031/S019	09/06/2016	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Removal of an in-process inspection for stent frames.
P140031/S021	09/08/2016	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE (THV), MODEL 9600TFX	EDWARDS LIFESCIENCES, LLC.	Reduce the sampling plan for the dimensional inspection and remove an inspection step in the manufacturing process of the cloth skirts used in the SAPIEN 3 THV.

Submission Number	Date Final Decision	Review Track	Trade Name	Appl/Spr Name	Approval Order Statement
P140031/S022	09/19/2016	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Implement an additional in-process flow tester at the Singapore facility.
P140031/S023	09/25/2016	X - 30-Day Notice	SAPIEN 3 TRANSCATHETER HEART VALVE	EDWARDS LIFESCIENCES, LLC.	Implementation of an upgraded laser for the manufacture of SAPIEN 3 Transcatheter Heart Valve frames at the Draper, Utah facility.
P150001/S001	09/30/2016	X - 30-Day Notice	MINIMED 630G PUMP	MEDTRONIC MINIMED	Relocation of the injection molding process for the 630G insulin pump case sub-assembly to a new manufacturing location. The insulin pump is a component of the MiniMed 630G System.
P150003/S020	09/29/2016	X - 30-Day Notice	SYNERGY EVEROLIMUS-ELUTING PLATINUM CHROMIUM CORONARY STENT SYSTEM	BOSTON SCIENTIFIC CORPORATION	Replace the black and white camera with a color camera on the Port Bond Inspection Station.
P150012/S014	09/13/2016	X - 30-Day Notice	INGENIO 2 PACEMAKERS, ESSENTIO, PROPONENT, ACCOLADE MRI MODELS	BOSTONSCIENTIFIC	Changes to visual inspection criteria for cosmetic defects.
P150012/S015	09/29/2016	X - 30-Day Notice	ESSENTIO MRI; PROPONENT MRI; ACCOLADE MRI PACEMAKERS	BOSTONSCIENTIFIC	Addition of a software interface between the traceability system software and the braze oven equipment for the feedthru component braze process.
P150047/S001	09/20/2016	X - 30-Day Notice	COBAS EGFR MUTATION TEST	ROCHE MOLECULAR SYSTEMS, INC.	Manufacturing scale increase for bulk manufacturing of components.

Total: 147